



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,987	03/13/2001	Christian Waeber	M0765/7035 (ERG/MAT)	9309

7590

09/24/2002

Edward R. Gates
c/o Wolf, Greenfield & Sacks, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02210-2211

EXAMINER

LI, RUIXIANG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 09/24/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/804,987

Applicant(s)

WAEBER ET AL.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12,23,34,43,56,66-70,77 and 86-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-12,23,34,43,56,66-70,77 and 86-114 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicants' election with traverse of Group II, Claims 34, 43, and 56, drawn to a method for treating a subject having, or at risk of having, a disorder which can be treated by increased vasodilation or inhibition of vasoconstriction, in Paper No. 10 filed on 08/21/2002 is acknowledged.
2. Applicants' amendment in Paper No. 10 filed on 08/21/2002 has been entered in full. Claims 87-115 have been added. Claims 1-12, 23, 34, 43, 56, 66-70, 77, and 86-114 are pending.
3. The amended claims 34, 43, and 56, and newly added claims 86-114 are further restricted to one of the following inventions as required under 35 U.S.C. 121:
 - I. Claims 34, 43, 56 (all in part), 86, 87, 93 (in part), 94, 95, 101-105 (in part), 106, 107, 113 (in part), 114 (in part), drawn to a method for treating a subject having, or at risk of having, a disorder which can be treated by increased vasodilation or inhibition of vasoconstriction comprising administering to a subject in need of such treatment a sphingosine kinase inhibitor, classified in class 514, subclass 2.
 - II. Claims 34, 43, 56 (all in part), 88-91, 93 (in part), 96-99, 101-105 (in part), 108-111, 113 (in part), 114 (in part), drawn to a method for treating a subject having, or at risk of having, a disorder which can be treated by increased vasodilation or inhibition of vasoconstriction comprising administering to a subject in need of such treatment an EDG receptor inhibitor, classified in class 514, subclass 2.

Art Unit: 1646

III. Claims 34, 43, 56 (all in part), 92, 93 (in part), 100, 101-105 (in part), 112, 113 (in part), 114 (in part), drawn to a method for treating a subject having, or at risk of having, a disorder which can be treated by increased vasodilation or inhibition of vasoconstriction comprising administering to a subject in need of such treatment a sphingosine-1-phosphate phosphatase activator, classified in class 514, subclass 2.

4. The inventions are distinct, each from the other for the following reasons. Inventions I-III are distinct, each from the other, because each group of invention is drawn to a method for treating a subject having, or at risk of having, a disorder which can be treated by increased vasodilation or inhibition of vasoconstriction comprising administering a different agent to a subject in need of such treatment. Each of these agents, a sphingosine kinase inhibitor, an EDG receptor inhibitor, a sphingosine-1-phosphate phosphatase activator, represents a structural and functionally distinct entity that is capable of supporting a separate patent. The search and consideration of more than a group of invention constitutes an undue search burden on the office.
5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
6. Because these inventions are distinct for the reasons given above and the search required for a single group is not required for any other group, restriction for examination purposes as indicated is proper.

Art Unit: 1646

7. This application contains claims directed to patentably distinct species as set forth below. These species require non-cohesive searches and considerations.

- (i) Claims 87, 95, and 107 contain six species of sphingosine kinase inhibitors as listed in each claim.
- (ii) Claims 89-91, 97-99, and 109-111 contain six species: an EDG-1 receptor inhibitor, an EDG-3 receptor inhibitor, an EDG-5 receptor inhibitor, an EDG-8 receptor inhibitor, sphingosine, and suramin.
- (iii) Claims 104 and 105 contain numerous species of second agents to be administered, as listed in the claims.

Should applicants elect a group containing these claims, applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37

Art Unit: 1646

CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02 (a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Art Unit: 1646

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
September 19, 2002



ELIZABETH KEMMERER
PRIMARY EXAMINER